National Environmental Laboratory **Accreditation** Conference

# ON-SITE ASSESSMENT

PROPOSED

June 2, 2003

Note that the NELAC standards now have two significant dates: 1) the date the standards were approved at the annual meeting, and 2) the date the standards are effective and must be implemented. This is especially important as some portions of the standards have different effective dates. The approval date is part of the document control header on each page. The cover of each chapter shows both the approval date and the effective date. Changes approved for implementation at a time other than the effective date (on the chapter cover) are noted in the chapter, showing the approved text and its effective date.

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*NOTE: Additions (double-underlined) and ~~deletions~~ (struck through) to the approved standards being proposed for vote at the next Annual Meeting are marked as in this note.*

## 3.0 ON-SITE ASSESSMENT

### 3.1 INTRODUCTION

The on-site assessment is an integral and requisite part of the NELAC laboratory accreditation program and is one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team[1] collects and evaluates information and makes observations which are used to judge the laboratory's conformance with established accreditation standards.

It is essential that the on-site assessments conducted by all accrediting authorities recognized by the National Environmental Laboratory Accreditation Program be conducted in a uniform, consistent manner.

This section describes the essential elements that must be included in any acceptable on-site assessment and the qualifications and requirements for assessors.

The responsibility for promulgating and enforcing occupational safety and health standards rests with the U.S. Department of Labor. While it is not within the scope of the assessment team to evaluate all health and safety regulations, any obviously unsafe condition(s) observed should be described to the appropriate laboratory official and reported to the accrediting authority. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with any applicable health and safety regulations.

### 3.2 ON-SITE ASSESSMENT PERSONNEL

#### 3.2.1 Basic Qualifications

An assessor must be an experienced professional and hold at least a Bachelor's degree in a scientific discipline or have equivalent experience in environmental laboratory assessment.

Each assessor must satisfactorily complete a training program approved by the accrediting authority responsible for on-site assessments. Each accrediting authority shall be responsible for ensuring that the training course used to train its assessors meets the NELAC standards. This program shall include:

a) Participation in the NELAC Basic Training Course (Section 3.2.3.1 and Appendix A), including attainment of a passing score on the written examination for the course;

b) Participation in at least four actual NELAC on-site assessments under the supervision of a qualified assessor (Assessors employed by an accrediting authority [either directly or as a

[1] An assessment team is comprised of a lead assessor, and one or more assessors or technical specialists. In some cases a single lead assessor may conduct an On-site assessment. In those instances the single assessor is considered the "team."

third party] when the accrediting authority is granted NELAP recognition [See Section 6.7] are exempt from the requirement to undergo training with a qualified assessor, provided they have previously conducted four assessments and been judged proficient by the accrediting authority.) and,

c) Completion of the applicable technical training requirements for at least one field of accreditation (Section 3.2.3.2 and Appendix B).

Assessors must take annual refresher/update training as defined in Section 3.2.3.3. In addition, the assessors must:

a) Be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;

b) Have a thorough knowledge of the relevant assessment methods and assessment documents;

c) Be thoroughly familiar with the various forms of records described in Section 3.5.3 - Records Review;

d) Be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;

e) Have a working knowledge and be conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling and preservation procedures; and,

f) Be able to communicate effectively, both orally and in writing.

### 3.2.2 Assessor Qualification

Before an assessor can conduct on-site assessments, an accrediting authority must qualify the individual. Each assessor must sign a statement before conducting an assessment certifying that no conflict of interest exists and provide any supporting information as required by the accrediting authority. Failure to provide this information makes the proposed assessor ineligible to participate in the assessment program.

### 3.2.3 Training

The National Environmental Laboratory Accreditation Conference (NELAC) specifies the minimum level of education and training for assessors, including refresher/update training. The NELAC also develops standards for training requirements. The assessor training program is implemented by either accrediting authorities, assessor bodies, or other entities. All assessor training programs, must meet the standards defined in this Chapter.

#### 3.2.3.1 Basic Training

The purpose of the basic assessor training is to familiarize the assessor with the NELAC standards and the skills and techniques associated with the laboratory assessment. The basic assessor training course shall encompass all the material described in Appendix A.

The specific training associated with the NELAC standards is required and must be successfully completed. All assessor candidates must pass the written examination.

**3.2.3.2 Technical Training**

In addition to the basic NELAC assessor training, each assessor must successfully complete training in at least one technical discipline.

The technical training program is defined in Appendix B. The purpose of the technical training is to ensure consistency of knowledge and techniques among the NELAC assessors. The technical training assumes a level of basic knowledge of the subject and concentrates on the elements of the technology or methods that are key to properly assure laboratory competency to deliver data of known and documented quality. The technical training program consists of the following :

NELAC Technical Training for Assessors

TECHNICAL DISCIPLINES

1. Microbiology
   - **S** Bacteriology
   - **S** Viruses/Parasites
   - **S** Microscopic Particulate Analysis (MPA)

2. Biological
   - --Whole Effluent Toxicity (WET) Testing
   - --Sediment Toxicity Testing and Variants
   - --Soils Toxicity Testing
   - --Specialized Toxicity Testing
   - --Taxonomy and Community Structure

3. Inorganic - Nonmetals/Misc.
   - **S** Spectrophotometric
   - **S** Titrimetric
   - **S** Potentiometric
   - **S** Colorimetric
   - **S** TOC/TOX
   - **S** Residue/Solids
   - **S** COD/BOD
   - **S** IR
   - **S** IC

4. Inorganic - Metals
   - **S** FAA
   - **S** GFAA
   - **S** ICP
   - **S** ICP/MS
   - **S** Sample Preparation (Digestion/TCLP/etc.)

5. Organics
   - **S** Sample Preparation
   - **S** HPLC
   - **S** GC
   - **S** GC/MS
   - **S** Instrument Software

6. Asbestos
   - **S** Bulk
   - **S** Air
   - **S** Water/TEM

7. Radiochemistry

8. Field Activities
   - **S** Source/Ambient Testing (CAA, RCRA, TSCA)
   - **S** e.g. Air Source Testing
   - **S** Basic Principles of Manual Methods
   - **S** Basic Principles of Instrumental Methods
   - **S** Soil/Groundwater (SARA, RCRA, TSCA, FIFRA)
   - **S** Surface Water (CWA, RCRA, TSCA, FIFRA)
   - **S** Drinking Water (SDWA)
   - **S** Multi-media (mix of above)
   - **S** Biological

#### 3.2.3.3 Refresher Training

The purpose for requiring refresher/update training for all assessors is to ensure that the assessors are aware of changes to the standards and/or approved analytical methodology as they occur and to enhance and improve skills associated with assessment. Assessors are expected to maintain proficiency on an on-going basis. Assessors must complete refresher/update training annually. Initially, the refresher/update training is conceptualized as follows:

NELAC Refresher/Update Training for Assessors

- **S** Changes to the NELAC Standards and the Resulting Checklist Changes
- **S** New Interpretations of the NELAC Standards
- **S** Technical Changes Associated with Approved Methodology and the Resulting Checklist Changes
- **S** Assessment Skills and Techniques
- **S** Current Developments

## 3.3 FREQUENCY AND TYPES OF ON-SITE ASSESSMENTS

### 3.3.1 Frequency

The accrediting authority must conduct a comprehensive on-site assessment of each laboratory prior to granting accreditation, except as allowed by interim accreditation (see Section 4.5.1). In addition, an on-site assessment of each accredited laboratory must be completed at least every two years. Assessments for cause are conducted more frequently, at the option of the accrediting authority.

### 3.3.2 Follow-up On-site Assessments

If directed by an accrediting authority, an assessment team must conduct follow-up assessments at laboratories where a deficiency was identified by the previous assessment. These assessments may be, but are not necessarily limited to, determining whether a laboratory has corrected its deficiency(ies), or determining the merit of a formal appeal from the laboratory. When deficiencies are of such severity as to possibly warrant the downgrading of a laboratory's accreditation status, any follow-up assessment that is planned or conducted must be completed and reported within thirty (30) calendar days after the receipt of the laboratory's plan of corrective action.

Nothing in this section should be construed as requiring an accrediting authority to reassess a facility prior to taking a regulatory or administrative action affecting the status of the facility's accreditation. Nothing in this section should be construed as limiting in any way the accrediting authority's ability to revoke or otherwise limit a laboratory's accreditation upon the identification of such deficiencies as to warrant such action.

### 3.3.3 Changes in Laboratory Capabilities

When a change occurs in a laboratory's ownership, location, key personnel, or major instrumentation, notification of the accrediting authority is required within 30 days (see Section 4.3.2). The accrediting authority must evaluate the significance of a change that might alter or impair the laboratory's capability and quality, and indicate to the laboratory the results of their evaluation in writing. The accrediting authority must retain records to indicate that such an evaluation was conducted.

### 3.3.4 Announced and Unannounced Visits

The accrediting authority, at its discretion, conducts either unannounced or announced on-site assessments. The accrediting authority is not required to provide advance notice of an assessment.

To the maximum extent practical, accrediting authorities shall, when necessary, work with Federal departments/agencies/contractors to obtain government security clearances for their assessment team as far in advance as possible. Federal departments/agencies/contractors shall facilitate expeditious attainment of the necessary clearances.

## 3.4 PRE-ASSESSMENT PROCEDURES

### 3.4.1 Assessment Planning

A good assessment begins with planning, which starts before the assessment team visits the laboratory. Planning is the means by which the lead assessor identifies all the required activities to be completed during the assessment process. Planning includes conducting a thorough review of NELAP and/or State records pertaining to the laboratory to be inspected. This saves time because familiarity with the operation, history, and compliance status of the laboratory increases the efficiency and focus of an on-site visit.

Pre-assessment activities include: determining the scope of the assessment; reviewing NELAP/State information; providing advance notification of the assessment to the laboratory, when appropriate; obtaining any security clearances and determining any special safety procedures which may be necessary; coordinating the assessment team; and gathering assessment documents. Section 3.4.5 discusses Confidential Business Information (CBI) issues.

#### 3.4.1.1 Assessment Team

It is encouraged that teams directed by a lead assessor perform assessments. A single assessor knowledgeable in the discipline, methods, and regulations applicable to the laboratories he or she assesses can competently perform some on-site assessments.

The accrediting authority determines the number and expertise of the assessment team and support personnel that are required to conduct the on-site assessment based on the type of assessment and the scope of accreditation of the accredited or applicant laboratory.

#### 3.4.1.2 Technical Support Personnel

An assessment team may include technical support personnel approved by the primary accrediting authority as capable of providing assistance to the assessors. These individuals need not be formally qualified by the accrediting authority as assessors (see Section 3.2.2). If not so qualified, these individuals must still meet the requirements of the standards concerning conflicts of interest and professional conduct. Members of the assessment team who provide technical assistance but are not qualified as assessors are not eligible to conduct interviews in the absence of the assessor nor to cite deficiencies.

### 3.4.2 Scope of the Assessment

The first step in the assessment planning process is deciding the extent of the assessment. The assessment must include both an appraisal of the laboratory's operations and a review of the appropriate records. The assessment for a field of accreditation must cover the complete scope of accreditation for which the laboratory seeks or maintains accreditation within the specific field of accreditation as authorized by the accrediting authority.

#### 3.4.2.1 Laboratory Assessments

A laboratory assessment must review the ability of the laboratory to conduct environmental testing. The examination of the systems, processes and procedures of the laboratory should give a general sense of its past and present capabilities to perform work of known and documented quality. During a laboratory assessment, the assessment team must identify a number of samples or a

recently completed or on-going project and evaluate to what extent the tests are being conducted according to the NELAC standards.

#### 3.4.2.2 Records Review

The purpose of a records review is to determine whether the testing laboratory has maintained necessary documentation of data, the quality system, and other information to technically substantiate reports previously issued. During a records review, the assessment team conducts an overall assessment of data and compares the data with submitted reports to determine whether the data collected, generated, and reported follow the NELAC standards.

### 3.4.3 Information Collection and Review

Prior to initiating an on-site assessment, the assessment team shall make determinations as to which laboratory records they wish to review prior to the actual site visit. These records, from the files of the accrediting authority, the national laboratory accreditation database, or the laboratory itself include, but are not limited to:

a) Copies of previous assessment reports and proficiency testing sample results;

b) General laboratory information such as laboratory submitted self-assessment forms, SOPs and Quality Manual(s);

c) Official laboratory communications and associated records with appropriate accrediting authority staff;

d) Available documents from recipients of reports from the laboratory;

e) The laboratory's application for accreditation;

f) The existing program regulations (federal and state), and

g) The most recently approved or in use laboratory methods for which the laboratory has requested or maintains accreditation.

### 3.4.4 Assessment Documents

Documents necessary for the assessment must be provided to the laboratory management or staff and assembled before the assessment, whenever possible. The lead assessor must obtain copies of all forms required for the assessment, including the appropriate checklist(s). Other types of documents include:

- Assessment Confidentiality Notice;
- Conflict of Interest Form;
- Assessor Credentials;
- Assessment Assignment(s);
- Assessment Notification Letter;
- Attendance Sheet(s) (opening and closing conference); and
- Assessment Appraisal Form.

In addition, the lead assessor must provide information to the laboratory on how to obtain assessment information from the accrediting authority.

### 3.4.5 Confidential Business Information (CBI) Considerations

During assessments, if the assessment team comes into possession of information claimed as business confidential, the laws and regulations of the primary accrediting authority will govern the procedures for handling and disclosure of this information. If the primary accrediting authority is not subject to laws or regulations pertaining to confidential business information, the EPA regulations for handling confidential business information, detailed in Title 40, Code of Federal Regulations, Part 2, Subpart B, will apply. Subpart B defines a business confidentiality claim as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." The assessment team must inform the responsible laboratory official at the beginning of the assessment of their right to claim any portion of the information requested during the assessment as CBI. The assessment team must describe any procedures that the laboratory must follow to claim information as CBI. Assessors must have training on handling claims of CBI. The assessors must be familiar with the procedures for asserting a CBI claim and handling information that contain the information claimed as CBI. The assessment team must take custody of all CBI information before leaving the laboratory, and must maintain it in custody, using all proper procedures and safeguards, until it can be received by an authorized official of the accrediting authority, who must also treat such information as CBI, until an official determination has been made in accordance with federal or State laws and regulations.

Certain actions are required of the responsible laboratory official when claiming information as business confidential. The laboratory representative must place on (or attach to) the information at the time it is submitted to the assessor, a cover sheet, stamped or typed legend, or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Allegedly confidential portions of otherwise non- confidential information should be clearly identified by the business, and may be submitted separately to facilitate identification and handling by the assessor. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. If the information claimed as business confidential suggests the need for further action, the information may be forwarded to the appropriate agency that may take further action outside the scope of the accreditation process, to obtain the client's identity. If the information claimed as business confidential suggests the need for further enforcement action, the accrediting authority is responsible for ensuring that all CBI issues are handled in accordance with applicable state or federal laws and regulations.

If a business confidentiality claim is received after the on- site assessment by the accrediting authority, the accrediting authority should make such efforts as are administratively practical to associate the late claim with copies of the previously submitted information in its files. However the accrediting authority cannot assure that such efforts will be effective in light of the possibility of prior disclosure or dissemination of the information.

It is not the responsibility of members of the on-site assessment team to make any determination with respect to the validity of a confidential business information claim; this responsibility rests with the accrediting authority. The assessor must maintain custody of CBI-claimed information collected during the assessment until they are delivered to an authorized official of the accrediting authority. CBI-claimed information may be the intellectual property of the laboratory. Therefore, all CBI-claimed information must be held in a secure manner throughout the holding period of assessment records and may not be reproduced or distributed

If the accrediting authority questions the claim that certain information is CBI, host laboratory must be contacted and given twenty-one (21) calendar days to:

1) provide justification of their claim to CBI,

2) remove the claim of CBI,

3) resolve the issue in a manner agreeable to both the laboratory and the accrediting authority,

4) engage legal assistance,

5) appeal the action in accordance with the NELAC standards, or

6) withdraw their NELAC accreditation application for the field of accreditation associated with the CBI information.

The accrediting authority shall notify the laboratory technical director of all decisions regarding the acceptance or denial of a claim of CBI within the time frames established by applicable state or federal laws and regulations. If no time frames are specified, the accrediting authority shall notify the laboratory technical director of a decision regarding the acceptance or denial of a claim of C.B.I. within 30 calendar days of receiving the claim. In no instance shall the accrediting authority declassify CBI- claimed information without notification of the laboratory.

#### 3.4.6 National Security Considerations

Assessment teams performing assessments at laboratories owned and/or operated by Federal departments/agencies/contractors must review the need for security clearances, appropriate badging, and/or a security briefing before proceeding with the on-site assessment. The laboratory must inform the assessors in writing of any information, including data, that is controlled for national security reasons and cannot be released to the public.

NELAP assessment teams performing an on-site assessment of a Federal agency may need security clearances, appropriate badging, and/or a security briefing before proceeding with the on-site assessment. Assessors shall be informed in writing of any information that is controlled for national security reasons and cannot be released to the public.

### 3.5 ASSESSMENT PROCEDURES

#### 3.5.1 Length of Assessment

The length of an on-site assessment depends upon a number of factors such as the scope of accreditation, the number of assessors available, the size of the laboratory, the number of problems encountered during the assessment, and the cooperativeness of the laboratory staff. The accrediting authority must assign an adequate number of assessors to complete the assessment within a reasonable period of time. Assessors must strike a balance between thoroughness and practicality, but in all cases must determine to what extent the laboratories' operations meet NELAC standards.

### 3.5.2 Opening Conference

Arrival at the facility for routine NELAC assessments occurs during established working hours unless special arrangements are made with the laboratory.

A laboratory's refusal to admit the assessment team for assessment results in an automatic failure of the laboratory to receive accreditation or loss of an existing accreditation by the laboratory, unless there are extenuating circumstances that are accepted and documented by the accrediting authority. The assessment team leader must notify the accrediting authority as soon as possible after refusal of entry.

An opening conference must be conducted and shall address the following topics:

a) the purpose of the assessment;

b) the identification of the assessment team;

c) the primary areas that will be examined;

d) any pertinent records and operating procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing the assessment team with the necessary documentation;

e) the roles and responsibilities of key managers and staff in the laboratory;

f) the procedures related to Confidential Business Information;

g) any special safety procedures that the laboratory may think necessary for the protection of the assessment team while in certain parts of the facility (under no circumstance is an assessment team required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a member of the assessment team during an inspection to gain access to the facility);

h) the standards that will be used by the assessment team in judging the adequacy of the laboratory operation;

i) the confirmation of the tentative time for the exit conference;

j) the presentation of the assessment appraisal form to the responsible laboratory official for submittal to the accrediting authority; and

k) the discussion of any questions the laboratory may have about the assessment process.

### 3.5.3 On-site Laboratory Records Review and Collection

Assessment team members must review laboratory records for accuracy, completeness and the use of proper methodology. NELAC Chapter 5, Section 5.12 lists the records required for review during the assessment. The assessors must document the required elements of the records review on the NELAC assessment checklists.

The laboratory must mark all confidential information. The lead assessor must handle it as required by appropriate laws and regulations. All other information for all aspects of application, assessment and accreditation of laboratories is considered public information. If the laboratory requests that information is confidential, the information must be treated as confidential until a ruling can be made by the accrediting authority.

### 3.5.4 Staff Interviews

As an element of the assessment process, the assessment team evaluates the analysis process by requesting that the analyst(s) normally conducting the test(s) give a step-by-step description of exactly what is done and what equipment and supplies are needed to complete the analysis. Any deficiencies shall be noted and discussed with the analyst~~. The deficiencies~~ and must be discussed again in the closing conference unless otherwise provided in Section 3.5.5.

The assessment team members shall have the authority to conduct interviews with any/all staff**.** Calculations, data transfers, calibration procedures, quality control/assurance practices, adherence to SOPs and report preparation shall be assessed for the complete scope of accreditation with the appropriate analyst(s).

### 3.5.5 Closing Conference

The assessment team must meet with representative(s) of the laboratory following the assessment for an informal debriefing and discussion of findings. ~~It should be noted that t~~The assessment team shall in no way ~~limits~~be limited in its ability to identify additional problem areas in the final assessment report should it become necessary. The assessment team shall provide only preliminary determinations of potential findings, their severity, and whether they are critical in nature, and must inform the laboratory that final determinations concerning the number, nature, and extent of assessment findings shall be made by the accrediting authority, after reviewing reported findings. The ~~members of the~~ assessment team must describe all deficiencies identified-to-date during the closing conference with the possible exception of any issues of improper and/or potentially illegal activity, which may be the subject of further action.

In the event the laboratory disagrees with the findings of the assessor(s), and the team leader adheres to the original findings, the deficiencies with which the laboratory takes exception shall be documented by the team leader and included in the report to the ~~accreditation~~accrediting authority for consideration. The accrediting authority ~~makes~~ shall make a determination as to the validity of the contested elements.

The assessment team must inform the laboratory representative(s) that an assessment report encompassing all relevant information concerning the ability of the applicant laboratory to comply with the accreditation requirements is forthcoming.

### 3.5.6 Reporting Procedures

The assessment team shall summarize potential assessment findings for the accrediting authority to consider. The accrediting authority shall make final determinations of the validity and severity of the potential findings identified by the assessment team. The accrediting authority or its authorized third party must present an assessment report identifying all confirmed findings to the laboratory within thirty (30) calendar days of the assessment.

The laboratory has thirty (30) calendar days from the date of receipt of the report to provide a plan of corrective action to the accrediting authority (see Section 4.1.3). ~~An exception to these deadlines is in~~In those circumstances where a possible enforcement investigation or other action has been initiated~~.~~, an exception to these deadlines is allowed. The laboratory shall give priority to correcting critical findings identified or confirmed by the accrediting authority.

### 3.5.7 Assessment Closure

After reviewing ~~the assessment report and~~ any completed corrective action(s) reported by the laboratory, the accrediting authority ~~makes~~shall make ~~the~~ a determination of the accreditation status for a laboratory. If the deficiencies listed in the initial assessment report are substantial or numerous, additional on-site assessments may be conducted before a final decision for accreditation following the procedures of the accrediting authorities.

## 3.6 STANDARDS FOR ASSESSMENT

### 3.6.1 Areas of Assessment

The areas to be evaluated during an on-site assessment to determine the competence of an environmental laboratory shall include:

a) Organization and Management

b) Quality System - Establishment, Assessments, Essential Quality Controls and Data Verification

c) Personnel

d) Physical Facilities - Accommodation and Environment

e) Equipment and Reference Materials

f) Measurement Traceability and Calibration

g) Test Methods and Standard Operating Procedures

h) Sample Handling, Sample Acceptance Policy and Sample Receipt

I) Records

j) Laboratory Report Format and Contents

k) Subcontracting of Analytical Samples

l) Outside Support Services and Supplies

m) Complaints

These areas must be evaluated against the standards detailed in Chapter 5, Quality Systems, Chapter 2, Proficiency Testing and Chapter 4, Accreditation Process of the NELAC Standards and the appropriate method references. Sufficient detail is provided in Chapter Five (5) and/or the

method reference(s) cited to enable accrediting authorities to evaluate laboratories consistently and uniformly.

### 3.6.2 Assessor's Role

The on-site assessor uses a variety of tools in the assessment process. The experience of the assessor, his/her observations, interviews with laboratory staff, and examination of SOPs, raw data, and the laboratory's documentation all play important roles in the assessment. The accreditation of a particular laboratory depends primarily upon the assessment team's findings. Much of the on-site assessment depends upon the assessor's observations of existing conditions (i.e. observing operations and processes). The recommendation not to accredit a laboratory, or to change a laboratory's accreditation status, must be based on factual information and not upon subjective evaluations. Therefore, it is crucial that the on-site assessor have a clear understanding of the laboratory's procedures and policies and that the assessor document any deficiencies in the assessment report of the On-site assessment. The assessment team must use specific documentation in its reporting of deficiencies.

During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information must be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team must present such information to the accrediting authority for appropriate action(s). These issues, at the discretion of the accrediting authority, may or may not be subjects or issues of the closing conference. However, the assessor must continue to gather the information necessary to complete the accreditation assessment.

### 3.6.3 Use of Checklists

Standardized checklists must be used for the on-site assessment. The use of checklists does not replace the need for assessor observations and staff interviews, but is another tool that assists in conducting a thorough and efficient assessment. A checklist is not a substitute for assessor training and experience.

### 3.6.4 Standards of Professional Conduct for Assessors

Professional standards apply to every NELAC assessor, whether a government employee or an employee of a third party organization conducting assessments under an agreement with a NELAP accrediting authority. Assessors that knowingly engage in unprofessional activity may be liable for punitive actions as initiated by the affected accrediting authority.

The Standards for Professional Conduct, as outlined in this section, are based upon 5 CFR 2635, "Standards of Ethical Conduct for Employees of the Executive Branch" and will be followed in NELAP related matters. NELAC assessors shall:

a) have no interest at play other than that of the accrediting authority and NELAC during the entire accreditation process;

b) act impartially and not give preferential treatment to any organization or individual;

c) provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and/or disability;

d) not use their position for private gain;

e) not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative, or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accrediting authority;

f) not hold financial interests that conflict with the conscientious performance of their duties;

g) not engage in financial transactions using information gained through their positions as assessors to further any private interest;

h) not engage in employment activities (seeking or negotiating for employment) or attempt to arrange contractual agreements with a laboratory that would conflict with their duties and responsibilities as an assessor;

i) not knowingly make unauthorized commitments or promises of any kind purporting to bind the affected accrediting authority and,

j) attempt to avoid any actions that could create even the appearance that they are violating any of the standards of professional conduct outlined in this section.

Assessors are reminded that it is their responsibility to report to the affected accrediting authority any personal issues or activities that constitute a conflict of interest before an assessment occurs. It is up to the affected accrediting authority to determine if the reported issues and activities regarding a specific assessor constitute, or be construed as, a conflict of interest. Appeals of decisions made by accrediting authorities regarding such matters must be directed to the Executive Director of the NELAC, who shall make the final decision as to the merit of such appeals.

### 3.7 DOCUMENTATION OF ON-SITE ASSESSMENT

#### 3.7.1 Checklists/Records

The checklists used by the assessors during the assessment shall become a part of the permanent file kept by the accrediting authority for each laboratory. The assessor shall specify the laboratory records, documents, equipment, procedures, or staff evaluated and the observations that contributed to the evaluation of "No" for each assessment checklist item. This information must be documented in the comments section or referenced on the checklist. The assessment report must contain sufficient evidence to support all assessment findings and the overall evaluation of the laboratory.

#### 3.7.2 Report Format

The final assessment report shall be written to contain a description of the adequacy of the laboratory as it relates to the assessment standards in Section 3.6.1. Assessment reports must be generated in a narrative format. Documentation of existing conditions at the laboratory must be included in each report to serve as a baseline for future contacts with the facility.

Assessment reports must contain:

a) Identification of the organization assessed (name and address),

b) Date of the assessment,

c) Identification and affiliation of each assessment team member,

d) Identification of participants in the assessment process,

e) Statement of the objective of the assessment,

f) Summary,

g) Assessment ~~observations~~, findings (deficiencies) and requirements.~~, and,~~

~~h) Comments and recommendations.~~

The Findings and Requirements section must be referenced to the NELAC standards so that both the finding (deficiency) is understood and the specific requirement is outlined. The team leader shall assure that the results within the final assessment report conform to established standards for the evaluated parameters.

~~The Comments and Recommendations section can be used~~ At the discretion of accrediting authorities, a section devoted to comments and recommendations can be included in assessment reports to convey suggestions ~~recommendations~~ aimed at helping laboratories ~~the laboratory~~ improve operations.

### 3.7.3 Distribution

The accrediting authority shall be recognized as having the responsibility for the distribution of the assessment reports. The assessment team leader shall compile, edit and submit the final report to the accrediting authority.

### 3.7.4 Release of On-site Assessment Report

On-site assessment reports must be released initially by the accrediting authority only. The reports will be released to the responsible laboratory official(s). The assessment report shall not be released to the National Accreditation Database and the public until findings of the assessment and the corrective actions have been finalized, all Confidential Business Information and information related to national security has been stricken from the report in accordance with prescribed procedures, and the report has been provided to the laboratory (see Section 4.1.3).

In accordance with the Freedom of Information requirements, any documentation adjudged to be proprietary, financial and/or trade information, or relevant to an ongoing enforcement investigation, must be considered exempt from release to the public.

### 3.7.5 Record Retention Time

Copies of all assessment reports, checklists, and laboratory responses must be retained by the accrediting authority for a period of at least five (5) years, or longer if required by specific State or Federal regulations (see Sections 4.3.3 & 5.12.2(b)).

# ON-SITE ASSESSMENT
## *APPENDIX A*

# NELAC BASIC ASSESSOR TRAINING

~~(Effective July 1, 2001)~~

# Appendix A - NELAC BASIC ASSESSOR TRAINING

## A.1 INTRODUCTION

Appendix A specifies the minimum standards for NELAC Basic Assessor Training Courses. This appendix must be used to design basic training courses for laboratory assessors. Appendix A and its technical counterpart, Appendix B, specify the principal elements of NELAC laboratory assessor training courses.

## A.2 COURSE PURPOSE

The purpose of the NELAC Basic Assessor Training Course is to fulfill the Basic Training requirement for assessors specified in Section 3.1 of the NELAC Standards.

The Basic Assessor Training Course:

- Instructs assessors on the basic elements of performing NELAC assessments by focusing on evaluating laboratory quality systems and the competency of the laboratory to perform the test methods on the scope of accreditation.
- Provides an overview of the NELAC Standards and the NELAP laboratory accreditation process.
- Promotes uniformity of laboratory assessments performed to obtain NELAP accreditation.
- Facilitates information exchange among assessors.

## A.3 COURSE LOGISTICS

The course subject matter and content must be organized in modules or discrete units. Although the order of instructional modules or units is not strictly prescribed, courses must be organized systematically and logically to allow the best assimilation and comprehension of their subject matter.

The course contents can be delivered in a traditional classroom, by teleconferencing, in computer on-line sessions, or by a combination of any of these media. The format for instruction modules or units must be appropriate to the subject matter and can include, but is not limited to, lectures, discussions, demonstrations, critiques, group exercises, written assignments, simulations, fictitious reenactments, or a combination of any of these. Regardless of the medium or format used for content delivery, all courses must provide opportunity for ample interaction between instructors and participants and, must include exercises designed to be completed by teams of participants.

### A.3.1 Duration

The duration of the course will depend upon the participants' experience and the course's mode of delivery, but must be sufficient to allow fulfilling all the objectives contained in section A.2 and to cover the content specified in section A.4.

### A.3.2 Providers, Instructors, and Participants

Providers of NELAC Basic Assessor Training Courses shall ensure that the number of instructors assigned to a course is commensurate with the number of participants attending and the delivery mode

of the course. Although other ratios of instructor to students may be acceptable, a typical Basic Assessor Training Course delivered in a traditional classroom setting assigns one instructor per every 15 participants.

Instructors must maintain credentials and qualification statements and must make them available to course participants or other interested parties.

Accrediting authorities shall approve training for their assessors. Providers of NELAC Basic Training Courses shall not claim NELAP approval of them and are restricted from using the NELAC and NELAP logos in any course or promotional materials.

This Appendix does not limit course participants to those employed by accrediting authorities. All participants, regardless of the course delivery mode, must register prior to taking a course. Providers must maintain records that identify participating students and their status (i.e. whether they have attended the course or completed one by passing an examination); however, it is the responsibility of accrediting authorities to qualify and approve their assessors.

Providers must update established courses and existing training materials to reflect any changes in effect made to the NELAC standards.

### A.3.3 Course Documentation Supplied to Participants, Final Examination, and Certificates

After receiving completed registration forms including fees (where charged), providers shall send participants a course agenda. The course agenda should contain titles of the instructional modules and units with a timetable, and should be sent to candidates in sufficient time to be read before the course. Providers must also provide with the agenda a copy of the NELAC Standards and the Quality System Checklist in effect at the time of the course.

### A.3.4 Final Examination

Participants must be offered an opportunity to take a written examination that quantitatively measures their knowledge of the NELAC standards and the course contents. Until such time as NELAP or a designated body can maintain a controlled set of questions to be used in written examinations, providers shall design their own questions and grading criteria. Participants that obtain 70% or more correct answers in the final examination are classified as successfully completing the course.

### A.3.5 Attendance or Completion Certificate

Course providers shall issue certificates to those participants who attend all the offered modules or instructional units and to those that successfully complete the course. A "Certificate of Attendance" containing a brief description of the course shall be issued to participants who choose not to take the final examination or who do not successfully complete the course, but who have attended all the modules or instructional units.

Participants that attend all the instruction modules and who successfully complete the course shall be issued a "Certificate of Completion".

### A.3.6 Appraisal of Course by Participants

Participants shall be offered an evaluation form at the end of the course to invite feedback to providers about the course's quality and content. Such forms shall be available to accrediting authorities and to NELAP upon request.

Providers are also encouraged to include in their courses an open session where participants evaluate a course and offer direct feedback to instructors.

### A.4 COURSE CONTENTS

The contents of the Basic Assessor Training Course must address the following items.

#### A.4.1 Introduction

The purpose of this module is to establish the intent and tone of the course. It should create an atmosphere that will encourage participation, feedback, and questions, and should clarify participant expectations about the intent and content of the course.

This module should provide an opportunity to:

1. Welcome participants
2 Introduce course content
3. Describe method of assessment of participants
4. Describe administrative and physical arrangements (e.g. lunches, telephone, timing)
5. Have participants introduce themselves

#### A.4.2 Historical Perspective on National Accreditation

This course module will provide a background on laboratory accreditation and the history included Chapter 1 of the NELAC standard. The historical perspective and overview of the requirements of assessors should enable participants to understand the benefits of national accreditation and how a uniform national accreditation process will improve the quality of environmental data.

1. The Need for National Accreditation
2. Past Efforts toward National Consistency
3. Genesis of the National Environmental Laboratory Accreditation Program (NELAP)

#### A.4.3 Fundamentals of NELAC and NELAP

The purpose of this module is to familiarize the course participants with the function and structure of NELAC, NELAP, and the essential role that the accrediting authorities have in the laboratory accreditation process. The module should establish for each participant a working knowledge of NELAC and the mechanics of the program.

What is NELAC?
1. Objectives of NELAC
2. Structure and Operation of NELAC
    a. NELAC Standards
3. What is NELAP?
    a. Current Status of NELAP
4. Structure and Operation of NELAP

5. Primary Accrediting Authorities
    a. Requirements and Functions of Primary Accrediting Authorities
    b. Process for Recognition of Accrediting Authorities
6. Secondary Accrediting Authorities
    a. Requirements and Functions of Secondary Accrediting Authorities
    b. Reciprocal Accreditation
7. National Accreditation Database
8. Scope of Accreditation

### A.4.4 Qualifications and Training Requirements for Assessors

The purpose of this module is to examine the requirements for becoming a qualified NELAC Assessor as defined in Chapter 3. At the end of the session each participant should understand the process and timing involved for becoming a NELAC assessor.

1. Basic Qualifications
    a. Qualification by an Accrediting Authority
    b. Absence of Conflict of Interest Certification
2. Purpose of Training Assessors
3. Basic Assessor Training
4. Technical Training
5. Refresher Training

### A.4.5 Accreditation of Laboratories

The purpose of this module is to define the NELAC laboratory accreditation process. Participants should understand the requirements of laboratories seeking accreditation and the process through which accreditation is granted.

1. Accreditation Requirements
2. Order of the Accreditation Process
3. Role of the Laboratory Assessor in Accreditation of Laboratories
4. Personnel Qualifications

### A.4.6 Proficiency Testing

The purpose of this module is to provide a comprehensive view of the role that the proficiency testing (PT) plays in the accreditation process. Participants should understand the importance of proficiency testing, the requirements for PT providers and laboratories, and the elements of the PT process that should be assessed during the on-site assessment.

1. Purpose of Proficiency Testing
2. Definitions
3. Mechanisms, Criteria, Current Programs, Follow-Up Actions
4. Oversight and Delivery of Proficiency Testing Program
    a. Proficiency Testing Providers
    b. Proficiency Testing Oversight Body
    c. Primary Accrediting Authorities
5. Laboratory Requirements
    a. Types of PT Samples Required to be Analyzed
        i. PT Fields of Testing

   b. Frequency of PT Sample Analysis
   c. Requirements for Handling and Analyzing PT Samples
6. Role of the Laboratory Assessor in Reviewing PT Sample Data

### A.4.7 Ethical Conduct Standards for Assessors

This module will review the elements of ethical conduct of assessors, establishing an expectation that assessor conduct be "above reproach," and the consequences of unethical conduct. In addition, the module will examine circumstances when an assessor activity might constitute a potential conflict of interest, and the need for disclosure. At the end of this session, participants should know the NELAC expectations and requirements for assessor conduct.

1. Professional Conduct of Assessors
2. Defining, Determining, and Avoiding Conflicts of Interest for Assessors

### A.4.8 Quality Systems

This module establishes the fundamental components of a quality system and trains assessors on how to evaluate them. It requires a group exercise in which a laboratory's quality manual is evaluated for conformance with the NELAC Standards. This case study can be used to emphasize the importance of key quality system elements.

1. Definition of a Quality System
   a. Quality Assurance
   b. Quality Control
   c. Elements of a Quality System
2. Quality System Requirements for Laboratories
   a. Quality Manual
   b. Quality Assurance Policies and Procedures
   c. Standard Operating procedures
   d. Corrective Actions
   e. Document and Records Control
   f. Data Review and Evaluation
3. Monitoring and Effectiveness of the Quality System
   a. Internal Audits
   b. Management review

### A.4.9 NELAC Quality System Checklist

This module will explore the proper use of the Quality Systems Checklist, including how and when the checklist should be completed, and the techniques that a good assessor follows when using any checklist. At the end of this module, participants should be familiar with the Quality Systems Checklist and how it relates to NELAC Chapter 5. Participants will learn how to use the Quality Systems Checklist as an assessment tool, rather than as the primary vehicle of the assessment.

1. Purpose
2. Mandatory Use
3. Use of the Quality Systems Checklist Before, During, and After Laboratory Assessments
4. Procedure for Documentation of Findings

### A.4.10 Interviewing Techniques for Assessors

The purpose of this module is to instruct participants on good interviewing techniques and the personal dynamics of an on-site assessment. Participants will learn communication skills, including effective questioning techniques; methods for gathering information in an objective and professional manner; and potential ethical concerns. Group exercises and simulations are particularly effective in this sub-unit.

1. Utility of Interviews During Laboratory Assessments
2. Interview Structure
3. Verbal and Non-Verbal Communication
4. Modes of Gathering Information
5. Ways of Asking Questions
6. Dealing with Difficult Interviewees

### A.4.11 NELAC Laboratory Assessments

This module of the course presents all phases of the assessment process: pre-assessment, on-site assessment, and post-assessment activities. The session should instruct participants in the use of assessment tools (e.g., observation, interviewing, documentation review, and tracking) to review the quality system, documented test procedures, test method validation, and the technical competence of a laboratory.

1. Purpose of Assessments
2. Frequency and Types of Assessments
3. Phases of an Assessment

#### A.4.11.1 Pre-Assessment Activities

1. Planning an Assessment
   a. Scope of an Assessment
   b. Appointment of Lead Assessor and other Team Members
   c. Roles of Assessment Team Members
2. Document review
   a. PT Sample results
   b. Quality Manual
   c. Corrective Action Reports and Plans
3. Previous Assessment Reports
4. Preparation of Agenda and Schedule
5. Notifications

#### A.4.11.2 On-site Assessment Components

A “mock” assessment exercise can be used during this sub-unit to instruct participants on the components of on-site assessments.

##### A.4.11.2.1 Opening Conference

1. Schedule and Agenda
2. Assessment Appraisal Form
3. Confidential Business Information (CBI)

#### A.4.11.2.2 Facility Walk-Through

#### A.4.11.2.3 On-site Assessment Proper

1. Use of the Quality Systems Checklist
2. Detailed Tour and Observation of Operations
3. Staff Interviews
4. Calibration and Traceability of measurements
5. Data and Document review
6. Records retention and Reporting

#### A.4.11.2.4 Assessment Team Meetings

#### A.4.11.2.5 Closing Conference

1. Reporting Non-Conformances

### A.4.11.3 Post On-site Assessment Activities

During this sub-unit participants should be instructed on how to correctly cite instances of non-conformance in assessment reports as well as effective ways of formatting them. Critiques of fictitious reports, or a writing assignment in which participants write a report of a "mock" assessment are particularly effective in this sub-unit.

1. On-site Assessment Report
2. Report Format
3. Report Release
4. Corrective Action Reports in Response to On-site Assessment
5. Surveillance and Re-Assessment
6. Retention of Assessment Documents

### A.4.12 Handling Assessment Challenges

The purpose of this sub-unit is to identify effective methods of handling potential problems during an assessment. Participants should gain useful conflict resolution tools during this session. Group exercises and simulations can be used effectively in this sub-unit.

1. Dealing with Improper Practices and potentially Illegal Activities
2. Dealing with Unexpected Circumstances
3. Technical Disagreements
4. Absence of Key Laboratory Personnel
5. Hostile Reception
6. Conduct of Assessors During On-site Assessments

## A.5 COURSE SUMMARY AND CONCLUSIONS

This module should conclude the instructional components of the course. It should present a course review that gives a global perspective of the purpose of NELAC and the laboratory assessment process. Participants should be given an opportunity to ask final questions about specific aspects of the assessment and accreditation process at this time.

## A.6 FINAL EXAMINATION

The last module of the course is the final examination. The examination determines whether a participant has sufficient knowledge of the NELAC Standards and effective assessment procedures to be a NELAC assessor.

## A.7 REFERENCES

1. ILAC-G3; 1994, "Guidelines for training Courses for Assessors Used by Laboratory Accreditation Schemes"

# ON-SITE ASSESSMENT
# *APPENDIX B*

# TECHNICAL TRAINING COURSES FOR ASSESSORS

~~(EFFECTIVE JULY 1, 2001)~~

~~(Effective July 1, 2001)~~

# Appendix B - TECHNICAL TRAINING COURSES FOR ASSESSORS

## B.1 INTRODUCTION

The purpose of the technical training courses is to ensure consistency of technical knowledge among the NELAC assessors. Prerequisites for the training course for the assessor are:

1. Basic knowledge of the technology, i.e. familiarity with the principles and application of the technology used by the laboratory.
2. An understanding of Quality Systems.

The technical courses must concentrate on the elements and details of the technology and/or methods that are critical to assuring that the laboratory is implementing it or them properly.

Technical training courses provided to meet the requirements defined in Section 3.2.3 of the NELAC Standard must address the elements listed below. Assessor technical training courses must also focus on how to review these elements during the on-site assessment. The skills obtained during these training courses must also enable assessors to evaluate quality systems components present in the laboratory, as they relate to technical disciplines, to ensure compliance with the NELAC Standard.

## B.2 COURSE CONTENT

Technical training courses must provide, identify, or review:

- Basic theoretical and operating principles of the analytical technology and associated instrumentation and software.
- Critical steps and processes of the analytical technology or technique that must be executed to ensure quality data, including critical quality control (QC) measures and QC criteria based on the technology.
- Major sources of error, and how to control them, for the analytical technology or technique.
- Inappropriate procedures or practices for the analytical technology or technique.
- Key information required to document completely the reported results.
- Essential elements for assessing data generated.
- Ways to detect improper practices.
- Exercises in the evaluation of raw data to reported results.

The training course must also include an examination covering the material presented to ensure an understanding of the above elements. Results of the examination will be submitted to the accrediting authority for action. All attendees will receive a course certificate.

## B.3 COURSE OBJECTIVES

The assessors successfully completing the course shall have acquired the following:

1. Knowledge sufficient to assess the implementation of the technology by the laboratory.

2. An understanding as to how the technology is used in the various methods.
3. An understanding of the key elements of data packages, and raw data to review and check effectively.

# ON-SITE ASSESSMENT
*APPENDIX C*

# MINIMUM ELEMENTS FOR ACCREDITING AUTHORITY STANDARD OPERATING PROCEDURES FOR ON-SITE ASSESSMENTS

# Appendix C - MINIMUM ELEMENTS FOR ACCREDITING AUTHORITY STANDARD OPERATING PROCEDURES FOR ON-SITE ASSESSMENTS

## C.1 INTRODUCTION

Chapter 6 of the NELAC standard defines the process and criteria used by NELAP to determine whether an accrediting authority meets the standard required for recognition. Under this standard (Section 6.2.3.a.1), accrediting authorities are required to maintain documentation about the laboratory accreditation process. Section 6.3.3.1.3.b.8 also states that the accrediting authority's Quality Manual shall include the policies and procedures to implement the accreditation process. This appendix summarizes the elements to be included by accrediting authorities in SOPs describing on-site assessments of laboratories seeking NELAP accreditation.

At a minimum, the following elements shall be included in the SOPs to ensure consistency of laboratory assessments performed by accrediting authorities.

## C.2 PRE-ASSESSMENT

### C.2.1 Assessment Planning

C.2.1.1 Description of how the type of assessment is determined, e.g., initial, renewal, follow-up, etc.

C.2.1.2 Procedures for determining whether the assessment is announced or unannounced, the scope of accreditation (technology, matrix, method, analyte or analyte groups), the estimated time spent on-site, and the assessment team resources needed.

### C.2.2 Assessment Team

C.2.2.1 Qualifications, roles, and responsibilities of the assessment team members, e.g., lead assessor, assessors, and technical support personnel.

C.2.2.2 Assessment team procedures to be followed if improper or potentially illegal activities are encountered.

C.2.2.3 Circumstances under which the assessment may be terminated including how the assessment team communicates this to the accrediting authority.

### C.2.3 Laboratory Documents Review

C.2.3.1 Description of how the assessment team will identify and select specific laboratory documents and records for review before and during an on-site assessment as required in NELAC Sections 3.4.3, 3.5.3, and 5.12.

C.2.3.1.1 The assessment team may present preliminary findings before the on-site assessment so the laboratory has time to correct them before the assessment team arrival.

C.2.3.1.2 If the assessment team determines that the laboratory is not ready for an On-site assessment, the SOP shall describe the procedures for laboratory notification.

C.2.3.2 The laboratory documents review process, to be performed before and/or during the on-site phase of each assessment, shall include the following records:

C.2.3.2.1 The laboratory's accreditation application,

C.2.3.2.2 Previous assessment reports,

C.2.3.2.3 Proficiency Test sample results,

C.2.3.2.4 Official laboratory communications with the accrediting authority and associated records,

C.2.3.2.5 Laboratory organization charts,

C.2.3.2.6 Signature Log,

C.2.3.2.7 Personnel qualifications, experience and training,

C.2.3.2.8 Laboratory Quality Manual,

C.2.3.2.9 SOPs, including those for the test methods for which accreditation is sought,

C.2.3.2.10 Instrumentation and equipment,

C.2.3.2.11 Standard and reagent origin, receipt, preparation, and use,

C.2.3.2.12 Initial method validation studies,

C.2.3.2.13 Demonstrations of capability for each analyst,

C.2.3.2.14 Test method precision and accuracy,

C.2.3.2.15 Sample receipt and handling,

C.2.3.2.16 Internal audits,

C.2.3.2.17 Software documentation and verification, software and hardware audits, records of changes to automated data entries,

C.2.3.2.18 Annual management review,

C.2.3.2.19 Document control records,

C.2.3.2.20 Corrective action reports,

C.2.3.2.21 Complaints,

C.2.3.2.22 Subcontractor registry,

C.2.3.2.23 Measurement uncertainty calculations (currently needed for Radiochemical testing), and

C.2.3.2.24 An example client report.

### C.2.4 Accrediting Authority On-site Assessment Documents

Procedures used by the assessment team to assemble the following accrediting authority standardized documents and forms before an assessment**:**

C.2.4.1.1 Confidentiality Notice,

C.2.4.1.2 Conflict of Interest Form,

C.2.4.1.3 Assessor Credentials,

C.2.4.1.4 Assessment Notification Letter,

C.2.4.1.5 Attendance Sheets for opening and closing conferences,

C.2.4.1.6 Standardized checklists, and

C.2.4.1.7 Assessment Appraisal Form.

### C.2.5 Confidential Business Information

Procedures for handling Confidential Business Information (CBI) in compliance with federal or state laws and regulations.

### C.2.6 National Security Considerations

Procedures for handling security requirements at laboratories owned or operated by Federal departments, agencies, or their contractors.

## C.3 ASSESSMENT

### C.3.1 Opening Conference

Procedures for conducting the opening conference of an on-site assessment, addressing:

C.3.1.1 The scope and purpose of the assessment,

C.3.1.2 The schedule with a tentative time for the exit conference,

C.3.1.3 The NELAC Standard used for the assessment,

C.3.1.4 Identification of the assessment team,

C.3.1.5 Test methods to be examined,

C.3.1.6 Records and SOPs required,

C.3.1.7 Confidential Business Information,

C.3.1.8 National Security Considerations, if applicable,

C.3.1.9 Roles and responsibilities of the laboratory staff,

C.3.1.10 The assessment appraisal form,

C.3.1.12 Laboratory safety procedures to be followed by the assessment team (lab coats, safety glasses, etc.)

### C.3.2 On-site Records Review and Collection

Procedures and criteria used by the assessment team to determine the accuracy and completeness of the records reviewed or collected on-site, including:

C.3.2.1 Number or scope of records selected for each type specified in NELAC Chapter 5, Section 5.12.

### C.3.3 Assessment Areas

C.3.3.1 Procedures for evaluating the following assessment areas against the NELAC Chapter 5 standard, including the types of objective evidence needed to demonstrate conformance with the standard (e.g. records, assessors observation, or interviews):

C.3.3.1.1 Organization and Management,

C.3.3.1.2 Quality System,

C.3.3.1.3 Personnel,

C.3.3.1.4 Physical facility,

C.3.3.1.5 Equipment and reference materials,

C.3.3.1.6 Measurement traceability and Calibration,

C.3.3.1.7 Test methods and SOPs,

C.3.3.1.8 Sample handling, sample acceptance policy, and sample receipt,

C.3.3.1.9 Records,

C.3.3.1.10 Laboratory report format and contents,

C.3.3.1.11 Subcontracting of analytical samples,

C.3.3.1.12 Outside Support Services and supplies, and

C.3.3.1.1.3 Complaints.

### C.3.4 Staff Interviews

Procedures for conducting and documenting staff interviews.

### C.3.5 Closing Conference

Procedures to be followed for the closing conference, including:

C.3.5.1 The process used for presentation findings (deficiencies) ~~and observations~~ at the closing conference (e.g., written, checklist, verbal),

C.3.5.2 Discussion of deficiencies,

C.3.5.3 Notification that the assessment team may identify additional deficiencies in the final report and potential for a follow-up assessment,

C.3.5.4 Handling disputed findings,

C.3.5.4 When to expect the assessment report,

C.3.5.6 Timeframe for submission of the response, and

C.3.5.7 Schedule for renewal and reassessment.

## C.4 ASSESSMENT PROCEDURES FOR TEST METHODS

This section specifies the minimum performance elements of test methods and procedures for their evaluation during on-site assessments that must be included in the accrediting authority's SOPs.

### C.4.1 Performance Elements of Test Methods

Performance elements of test methods are those that directly affect data quality and data defensibility.
Although these elements apply to a broad range of test methods and analytical disciplines, assessors may at times encounter test methods for which some of these elements are not applicable. This possibility does not constitute an allowance for assuming the inapplicability of a performance element without an informed determination of this claim by a trained assessor.

In all cases, assessors must ensure that the specifications and criteria of performance elements of test methods are in conformance with the NELAC Standard.

C.4.1.1 Test Method Documentation

C.4.1.1.1 Written procedure conforming to Section 5.10 of the NELAC Standard.

C.4.1.1.2 Description of all steps necessary to determine the presence, identity, or concentration of an analyte in a sample.

C.4.1.1.3 Demonstrations of capability of all analytes or work cells performing the test method conforming to Section 5.10.2.1 of the Standard.

C.4.1.2 Laboratory Support Equipment

C.4.1.2.1 Availability and use of support equipment (e.g. thermometers, balances, volumetric devices).

C.4.1.2.2 Calibration of standardization procedures.

C.4.1.2.3 Maintenance procedures.

C.4.1.2.4 Corrective actions and contingency procedures undertaken in the event of equipment failure.

C.4.1.3 Reagents and Standards

C.4.1.3.1 Availability and use of reagents, standards, and biological media.

C.4.1.3.2 Purity of standards, reagents, and biological media.

C.4.1.3.3 Verification of identity and concentration of prepared standards.

C.4.1.4 Laboratory Instruments

C.4.1.4.1 Availability and use of analytical instruments.

C.4.1.4.2 Standardization, tuning, or instrument setup.

C.4.1.4.3 Calibration procedures including:

C.4.1.4.3.1 Calibration range.

C.4.1.4.3.2 Number and concentration of calibration standards.

C.4.1.4.3.3 Calibration algorithm.

C.4.1.4.3.4 Reduction of calibration data.

C.4.1.4.3.5 Frequency of calibration checks or of recalibration.

C.4.1.4.4 Maintenance procedures.

C.4.1.4.5 Corrective actions and contingency procedures undertaken in the event of instrument failure.

C.4.1.5 Sample Preparation and Analysis

C.4.1.5.1 Use of sample preparation techniques (e.g. filtration, aliquot selection, digestion, distillation, extraction).

C.4.1.5.2 Use of clean-up procedures.

C.4.1.5.3 Treatment of interferences before or during analysis.

C.4.1.5.4 Arrangement of analysis sequence or run.

C.4.1.6 Quality Control Indicators

C.4.1.6.1 Type and frequency of positive (Laboratory Control Samples), negative (Method Blanks), and sample specific (Matrix Spikes, Matrix Spike Duplicates, Matrix Duplicates, and Surrogates) controls.

C.4.1.6.2 Sensitivity and selectivity of analyses.

C.4.1.6.3 Acceptance criteria.

C.4.1.6.4 Corrective actions and contingency procedures undertaken when quality control indicators do not meet acceptance criteria.

C.4.1.7 Data Reporting and Documentation

C.4.1.7.1 Collection, documentation, and retrieval of raw data.

C.4.1.7.2 Raw data media (e.g. hard copy, electronic), storage, and security.

C.4.1.7.3 Capacity for reconstructing final results.

C.4.1.7.4 Chronology of data reduction operations.

C.4.1.7.5 Formulas used to derive quantitative results.

C.4.1.7.6 Procedures for confirming or verifying qualitative assessments of reported analytes.

C.4.1.7.7 Traceability of data to test methods, analysts, and instruments used to derive them.

C.4.1.7.8 Procedures for allowing manual correction of raw data (e.g. manual integration) and for overriding instrument qualitative results.

C.4.1.7.9 Procedures for data review.

**C.4.2 Evaluation Phases for Test Methods**

Assessors shall evaluate performance elements of test methods by completing the three phases specified below for a representative set of test methods from each analytical technology and at least Phase I (one) for all test methods used by a laboratory. This does not preclude an accrediting authority, when specified by a regulatory program, from requiring that assessors evaluate all test methods for all three phases.

C.4.2.1 Phase I – Laboratory SOPs or Methods Manuals

Assessors must confirm that SOPs or Methods Manuals:

C.4.2.1.1 Document all tests for which the laboratory requests or maintains accreditation,

C.4.2.1.2 Include or reference performance elements of test methods,

C.4.2.1.3 Are controlled in conformance to the laboratory's quality system and the latest revisions are in use.

C.4.2.2 Phase II - Verification of Proper Execution of Test Methods

Assessors must verify that analysts complete performance elements of test methods and determine whether analysts adhere to laboratory SOPs or Methods Manuals by:

C.4.2.2.1 Inspecting areas where test methods are performed and

C.4.2.2.2 Direct observation of analysts performing test methods and/or

C.4.2.2.3 Interviewing analysts that perform test methods or authorized laboratory representatives when analysts are unavailable.

C.4.2.3 Phase III - Audit of Data Generated Using Test Methods:

Assessors must ascertain that:

C.4.2.3.1 Results reported are traceable to their raw data.

C.4.2.3.2 Results reported can be traced back to calibration data and quality control indicators.

C.4.2.3.3 Documents associated with reported results validate or verify the correct execution of a test method.

## C.5 ASSESSMENT REPORTING

### C.5.1 Assessment Report:

The SOP shall specify the content and format of assessment reports. The assessment reports shall include, at a minimum:

C.5.1.1 Identification of organization assessed (name and address)

C.5.1.2 Date of the assessment,

C.5.1.3 Identification and affiliation of the each assessment team member,

C.5.1.4 Identification of participants in the assessment,

C.5.1.5 Statement of the objective or goal of the assessment,

C.5.1.6 Summary,

C.5.1.7 Identification of assessment ~~observations,~~ findings (deficiencies) and requirements with reference to the specific NELAC Standard(s).

~~C.5.1.8 Comments and recommendations.~~

**C.5.2 Roles and Responsibilities**

The SOP shall specify the roles and responsibilities of the assessment team and the accrediting authority in:

C.5.2.1 Report generation,

C.5.2.2 Report distribution,

C.5.2.3 Report release.

**C.5.3 Report Release**

The SOP shall specify the procedures for:

C.5.3.1 Assessment report release to the laboratory and to the public.

C.5.3.2 Handling of proprietary or confidential information.

**C.6 ASSESSMENT CLOSURE**

The SOP shall specify procedures, and the roles and responsibilities of the assessment team and the accrediting authority for:

C.6.1 Evaluating the laboratory's corrective action plan.

C.6.2 Ensuring that all required timeframes are met.

C.6.3 Determining a laboratory's accreditation status.

C.6.4 Performing a follow-up assessment and the minimum documentation required for such an assessment.

C.6.5 Retaining records used in or obtained during an assessment, including reports, checklists, and laboratory responses.